FEB 16 2001

Novartis Nutrition Corporation
Technical Center
1541 Park Place Boulevard
St. Louis Park MN 55416-1514

NOVARTIS

510(K) SUMMARY

COMPAT® REPLACEMANT BALLOON GASTROSTOMY TUBE KIT

SUBMITTER: Robert J. Lang
Novartis Nutrition Corporation
PO Box 370
Minneapolis, MN 55440
TEL: (952) 591-2950
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CONTACT PERSON: Sharon Martin

DATE PREPARED: February 16,2001

NAME OF DEVICE:

TRADE NAME: Novartis Nutrition Compat® Replacement Balloon Gastrostomy Tube Kit

COMMON NAME: Replacement Gastrostomy Tube Kit

CLASSIFICATION NAME: Gastrointestinal Tubes and Accessories (21 CFR 876.5980)

PREDICATE DEVICE(S): Novartis Nutrition Compat® Mini-G Replacement Gastrostomy Tube 510(k) Number K981323

Anti-microbial Mediastinal Wound Drainage Catheter with HealthShield 510(k) Number K991117

DESCRIPTION: The Replacement Gastrostomy Tube is a balloon style tube that is inserted through a well-established and mature stoma tract. The device is intended for single patient use.

INTENDED USE: The device delivers enteral formula and medications directly into the stomach and may be used for gastric decompression or drainage.

COMPARISON OF TECHNICAL CHARACTERISTICS:

The Compat® Replacement Balloon Gastrostomy Tube Kit has the same intended use as the Compat® Mini-G Replacement Gastrostomy Tube. Principle differences include:

- Angion Silver additives compared to no additives
- Radio-opaque material compared to radio-opaque material only in the tip
- Syringe activated inflation valve compared to syringe plus needle activated
- Two replaceable connection ports compared to one permanent port
- Colorant additive compared to no additive
- Two adjustable lengths compared to four lengths adjustable over 1 cm

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Robert .Lang
Director of Quality Operations
Novartis Nutrition Corporation
P.O. Box 370
5320 West 23rd Street
Minneapolis, Minnesota 55440

Re: K001916
Compat® Replacement Gastrostomy Tube Kit
Regulatory Class: II
21 CFR §876.5980/Procode: 78 KNT
Dated: November 16, 2000
Received: November 20, 2000

Dear Mr. Lang:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act). You may, therefore, market the device, subject to the general controls provisions of Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4616. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act, may be obtained from the Division of Small Manufacturers Assistance at its toll free number (800) 638-2041 or (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN): K001916

DEVICE NAME: COMPAT® Replacement Balloon Gastrostomy Tube Kit

INDICATIONS FOR USE:

The Novartis Nutrition COMPAT® Replacement Gastrostomy Tube is used as a replacement for surgically, laparoscopically or endoscopically placed gastrostomy tubes when an established, well-healed and mature tract (i.e. stoma tract) between the stomach and external body surface exists. The device delivers enteral formula and medications directly into the stomach and is intended for single patient use.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The Counter-Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-9)

David A. Flynn
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K001916